INFORMATION PAPER

MILVAX - VHCN
3 December 2013

SUBJECT: *Haemophilus Influenzae* type b and Hib vaccines

1. Purpose: To describe infection due to *Haemophilus Influenzae* type b (Hib) bacteria and the vaccines to prevent it.

2. Facts.

a. Microbiology. *H. influenzae* is a gram-negative coccobacillus. It is generally aerobic but can grow as a facultative anaerobe. The outermost structure of *H. influenzae* is composed of a polysaccharide that is responsible for virulence and immunity. There are six different serotypes of this bacterium but Type b accounts for 95% of all strains that cause invasive disease.

b. Disease. Hib organisms mainly colonize the nasopharynx but may invade the bloodstream causing an invasive infection. Invasive Hib can affect many organs and the most common clinical presentations are meningitis, epiglottitis, pneumonia, arthritis, and cellulitis. Of the presentations meningitis is most commonly seen. Symptoms of meningitis include fever, decreased mental status, and stiff neck. Less common forms of invasive disease include osteomyelitis and pericarditis. The mortality rate for invasive disease is 2%–5% and survivors may suffer permanent hearing impairment or neurologic damage.

c. Epidemiology. Hib occurs globally and humans are the only known reservoir. The bacterium is spread person-to-person by direct contact or through respiratory droplets. The transmission potential of invasive Hib disease is considered to be limited. However, certain circumstances, particularly close contact with a case-patient (e.g., household, child care, or institutional setting) can lead to outbreaks or direct secondary transmission of the disease. Children under the age of 5 are at the greatest risk as recent cases of Hib infections in the US were in unvaccinated children 5 years and under.

d. Vaccine.

(1) Act-HIB® is a conjugate vaccine produced by Sanofi Pasteur. The vaccine is a sterile, lyophilized powder that when reconstituted consists of polysaccharide conjugate, sucrose, diphtheria toxoid and thimerosal (when reconstituted with DPT vaccine).

(2) PedVaxHIB® is a conjugate vaccine produced by Merck. The vaccine is a sterile liquid that contains polysaccharide conjugate that is bound to *Neisseria meningitidis* and aluminum sulfate. The rubber stopper may contain latex.

(3) HIBERIX® is a conjugate vaccine produced by GlaxoSmithKline. The vaccine is a sterile, lyophilized powder that when reconstituted with the accompanying saline, consists of lactose, tetanus toxoid and formaldehyde. Prefilled syringe tip caps may contain latex.

(4) Three combination vaccines that contain Hib conjugate vaccine are also available. COMVAX® produced by Merck contains the Hib and Hep B antigens; Pentacel® produced by *S*anofi Pasteur contains DTaP, IPV and Hib; and MENHIBRIX® produced by GlaxoSmithKline contains meningococcal and Hib .

e. Immunization. Administer the primary series of Hib containing vaccine to infants at 2, 4, and 6 months of age. The number of doses in the primary series (2 or 3 doses) depends on which type of vaccine is used and the age of the child when the series is started. Administer each 0.5-mL dose intramuscularly into the anterolateral aspect of the thigh or deltoid muscle. The optimal interval between doses is 2 months, with a minimum interval of 4 weeks. A booster dose is recommended at 12 to 15 months, regardless of which brand was used earlier. Separate the booster dose from the previous dose by at least 8 weeks. Routine vaccination of children older than 59 months is not recommended. However, some older children and adults should be vaccinated as they may be at increased risk of invasive Hib disease caused by conditions such as sickle cell disease, HIV/AIDS, removal of the spleen, bone-marrow transplant, or cancer treatment.

f. Cautions. Vaccination with Hib conjugate vaccine is contraindicated for persons known to have experienced a severe allergic reaction to a vaccine component or a prior dose of that vaccine. Vaccination should be delayed for children with moderate or severe acute illnesses. Hib conjugate vaccines are contraindicated for children younger than 6 weeks of age because of the potential for the development of immunologic tolerance. Review package insert for latex allergy precautions.

g. Adverse Events. The most common adverse reactions to Hib vaccine are injection site reactions to include swelling, redness, and/or pain after the first dose. The incidence of these reactions declines with repeat doses. Systemic reactions, such as fever and irritability, are infrequent and serious adverse reactions are rare.

h. DoD Policy. Administer Hib vaccine in accordance with ACIP recommendations.

i. Special Considerations. None.

3. References.

a. Centers for Disease Control and Prevention. Haemophilus b Conjugate Vaccines for Prevention of *Haemophilus influenzae* type b Disease among Infants and Children Two Months of Age and Older. Recommendations of the Advisory Committee on Immunization Practices. MMWR 1991; 40(RR-01):1-7.

b. Centers for Disease Control and Prevention. Updated Recommendations for Use of *Haemophilus influenzae* Type b (Hib) Vaccine: Reinstatement of the Booster Dose at Ages 12–15 Months. MMWR 2009; 58 (24):673-674.

c. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by the MILVAX - VHCN: www.vaccines.mil/hib

Ms Celia Dowers/ (703) 681-5668

Approved by: Dr Limone Collins